REMARKS

I. Status Summary

Claims 1-18 and 20-22 are pending in the present application. Claims 1-11, 13, 14, 16-18, and 20-22 have been rejected by the U.S. Patent and Trademark Office (hereinafter the "Patent Office"). Claim 12 is withdrawn. Claim 15 is allowed.

Claims 1, 3, 7, and 13 have been amended. Withdrawn claim 12 has been amended. The specification has been amended. Claims 2, 5, 10, 11, 17, and 21 have been canceled. Support for the amendments can be found throughout the specification as filed. No new matter has been added. Therefore, upon entry of Amendment B, claims 1, 3, 4, 6-9, 13-16, 18, 20, and 22 will be pending in the subject application.

Reconsideration of the application as amended and further in view of the remarks set forth herein below is respectfully requested.

II. Allowable Subject Matter

The Patent Office has indicated that claim 15 is allowable to the extent that it reads upon camptothecin. The Patent Office has further indicated that the other species of claim 15 have been found to be free of the art.

Applicants gratefully acknowledge the Patent Office's indication of the allowability of claim 15. Applicants respectfully submit that claim 20 recites a composition comprising a conjugate according to claim 15, and, therefore, includes each and every element of claim 15. Claim 22 depends from claim 20, and, thus, also includes each and every element of claim 15. Accordingly, in view of the Patent Office's comments regarding claim 15, claims 20 and 22 are believed to be directed to allowable subject matter; and applicants respectfully ask that claims 20 and 22 be allowed at this time.

III. Response to Rejections under 35 U.S.C. § 112, First Paragraph,

Claims 1-11, 13, 14, 16-18, and 20-22 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Patent Office contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors were in possession of the claimed subject matter at the time the application was filed. More particularly, the Patent Office contends that claims 1 and 7 recite that "P" is a "water-soluble polymer" but that the specification has specific examples only relating to polyethylene glycol and an oligopeptide of glutamic acid. The Patent Office contends that claims 1 and 7 recite that "X" is a linking group, but that "X" is not adequately defined in the claim or the specification. The Patent Office alleges that while claims 1 and 7 recite that "TA" is a "drug molecule" and claim 15 recites that "PT" is a "drug molecule," the term "drug molecule" lacks proper definition in that the number of specific drug compounds disclosed is not commensurate with the scope of the claims as recited. Finally, the Patent Office alleges that claims 17 and 21 recite "another therapeutically active ingredient," but that the specification does not provide a proper definition for the term.

Without acquiescing to the rejection or the Patent Office's comments, applicants respectfully submit that, in an effort to expedite allowance of the subject application, claims 17 and 21 have been canceled, thereby rendering the rejection of claims 17 and 21 moot.

Further, again without acquiescing to the rejection or the Patent Office's comments, and also in an effort to expedite allowance to the subject application, applicants respectfully submit that claims 1 and 7 have been amended. More particularly, claim 1 has been amended to recite that P is a hydrophilic polymer selected from the group consisting of polyethylene glycol, polypropylene glycol, polyvinyl alcohol, polyacrylmorpholine and copolymers thereof; that X is a linking group selected from the group consisting of $(CH_2)_i$, $(CH_2)_iOCO$, $(CH_2)_iNHCO$ and $(CH_2)_iCO$, and wherein i is an integer from 0-10, inclusive; and that TA is a drug molecule selected from the group

consisting of organic acids, terpenoids, phenylpropanoid phenols, steroids, alkaloids, etoposide, and esters thereof. Support for the term "hydrophilic polymer" can be found in claims 1, 6, 7, and 8. Support can also be found in the instant specification at page 3, lines 21-23. Support for the recited hydrophilic polymers can be found in claim 2, and in the instant specification at page 3, lines 21-23. Support for the group recited for X can be found in claim 5. Support for the group recited for TA can be found in claims 10 and 14, and in the instant specification at page 8, lines 7-8 and line 15.

Claim 7 has been amended to recite that X is a linking group selected from the group consisting of $(CH_2)_i$, $(CH_2)_iOCO$, $(CH_2)_iNHCO$ and $(CH_2)_iCO$, and wherein i is an integer from 0-10, inclusive; and that TA is a drug molecule selected from the group consisting of organic acids, terpenoids, phenylpropanoid phenols, steroids, alkaloids, etoposide, and esters thereof. Support for the group recited for X can be found in claim 5. Support for the group recited for TA can be found in claims 10 and 14, and in the instant specification at page 8, lines 7-8 and line 15.

In view of the amendments to claims 1 and 7, claims 2, 5, 10, and 11 have been canceled. Claim 3 has been amended to depend from claim 1 and to recite "the hydrophilic polymer." Claim 13 and withdrawn claim 12 have been amended to depend from claim 1. The specification has been amended to recite that P is a hydrophilic polymer to correspond to the amendment to claim 1.

Accordingly, applicants respectfully request that the rejection of claims 1, 3, 4, 6-9, 13, 14, and 16-18 under 35 U.S.C. § 112, first paragraph, be withdrawn, and further ask that claims 1, 3, 4, 6-9, 13, 14, and 16-18 be allowed at this time.

In addition, as noted hereinabove, applicants respectfully submit that claim 20 recites a composition comprising a conjugate according to claim 15, and, therefore, includes each and every element of claim 15. Claim 22 depends from claim 20, and, thus, also includes each and every element of claim 15. Claim 15 recites that X is a linking group selected from the group consisting of $(CH_2)_i$, $(CH_2)_iOCO$, $(CH_2)_iNHCO$ and $(CH_2)_iCO$, and wherein i is an integer from 0-10, inclusive; and that PT is a drug molecule selected from the group consisting of paclitaxel, camptothecin, cinobufagin,

clycyrrhetinic acid, scopoletin, and esters thereof. Claim 15 does not recite a variable "P". Instead, claim 15 recites a structure including the group CH_3O-$(CH_2CH_2O)_n$-.

Accordingly, and particularly in view of the Patent Office's comments regarding the allowability of claim 15, applicants respectfully request that the rejection of claims 20 and 22 under 35 U.S.C. § 112, first paragraph, be withdrawn, and further ask that claims 20 and 22 be allowed at this time.

IV. Response to Rejections under 35 U.S.C. § 112, Second Paragraph,

Claim 7 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter regarded as the invention. In particular, the Patent Office contends that claim 7 recites the term "free hydroxyl" for which there is insufficient antecedent basis. The Patent Office contends that claim 1, from which claim 7 depends, does not have a structure having an available hydroxyl group.

After careful consideration of the rejection and the Patent Office's comments, applicants respectfully traverse the rejection and offer the following remarks.

Applicants respectfully submit that as described hereinabove, claim 1 has been amended to recite that P is a hydrophilic polymer selected from the group consisting of polyethylene glycol, polypropylene glycol, polyvinyl alcohol, polyacrylmorpholine and copolymers thereof. Applicants respectfully submit that one of skill in the art would understand that hydrophilic polymers such as polyethylene glycol, polypropylene glycol, and polyvinyl alcohol can comprise a free hydroxyl group. For example, polyethylene glycol (i.e., PEG), the structure of which (i.e., HO-$(CH_2CH_2O)_n$-CH_2CH_2OH) is shown at the top of Figure 1 of the instant specification, comprises two free hydroxyl groups. Even if one of the two free hydroxyl groups is substituted with X in the structure recited in claim 1, a remaining free hydroxyl is available for substitution by a structure having the formula recited in claim 7. Applicants note that Figure 1 of the instant specification shows a structure (i.e., **2**), wherein both free hydroxyls of a PEG molecule have been substituted by an oligopeptide comprising free carboxylic acid groups that can be conjugated to drug molecules via steps such as those shown in Figures 2 and 3.

Accordingly, applicants respectfully request that the rejection of claim 7 under 35 U.S.C. § 112, second paragraph, be withdrawn. Applicants also respectfully ask that claim 7 be allowed at this time.

CONCLUSIONS

Should there be any minor issues outstanding in this matter, the Examiner is respectfully requested to telephone the undersigned attorney. Early passage of the subject application to issue is earnestly solicited.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account Number **50-0426**.

Respectfully submitted,

JENKINS, WILSON, TAYLOR & HUNT, P.A.

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By: _____
Arles A. Taylor, Jr.
Registration No. 39,395

1547/2 AAT/ALO/dbp

Customer No: 25297